FEB 5 2013

K122183

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	July 20, 2012
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	Augment and Screw, PSA Type
Common Name:	Knee System Augments
Device Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	JWH
Predicate Device:	1. "UNITED" U2 Total Knee System – PSA Type (K082424) 2. "Zimmer" NexGen Complete Knee Solution Legacy CCK Type (K960279) 3. "BIOMET" Vanguard 360 Revision Knee System (K093293)

Device Description:

"UNITED" Augment and Screw – PSA Type, including femoral augments – distal only and tibial augments, is an extension of cleared "UNITED" U2 Total Knee System – PSA Type (K082424). The raw materials, safety and effectiveness of this subject device

are identical to the "UNITED" U2 Total Knee System – PSA Type (K082424), except for increasing their thickness and modifying the shape to mimic anatomy.

Femoral augment – distal only made of Co-Cr-Mo alloy (ASTM F75 or ASTM F1537) are available in 12 mm and 16 mm thickness and can be positioned on either side of femoral component. This component is only available distally. Tibial augments are made of Ti-6Al-4V alloy (ASTM F136/ISO 5832-3) and with 15 mm thickness. The periphery of the distal end of tibial augments is larger than that of the proximal end. It is left/right specific. The femoral augments and tibial augments are sized to match the femoral components and tibial base plates, respectively. There are 6 sizes (sizes #1 through 6) to match the corresponding augmentable femoral components – PSA type and tibial baseplates – PSA type (K082424). The augments are affixed to the tibial and femoral components with screw fixation and that the implant construct as a whole is to be fixed with cement. This device should not be used with another manufacturer's total knee systems since dimensional compatibility cannot be assured. It also should not be used with U2 Total Knee System – PS Type and CR Type. For total knee replacement, "UNITED" patella components (K021657, K051640, K082469, and K103733) are intended to be used with U2 Total Knee System – PSA Type (K082424) and the subject device.

Indications

This device is indicated in knee arthroplasty in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate

valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

Note: In the US, this device is for cemented use only.

Basis for Substantial Equivalence:

The intended uses, materials, locking mechanism design and sterilization method of femoral augments – distal only are similar to the femoral augments of U2 Total Knee System – PSA Type (K082424) and "Zimmer" NexGen Complete Knee Solution Legacy CCK Type (K960279). The differences between these three devices are 1) thickness, 2) geometry, and 3) the femoral screw length and its threaded length.

The intended uses, substrate materials, locking mechanism design and sterilization method of tibial augments are similar to the tibial augments of U2 Total Knee System – PSA Type (K082424) and "BIOMET" Vanguard 360 Revision Knee System (K093293). The differences between these three devices are 1) thickness, 2) geometry, and 3) edge taper.

Performance Data:

The locking strength evaluation between femoral component and femoral augment, as well as tibial baseplate and tibial augment completed as part of the design assurance process, demonstrated that this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
Regulatory Affairs, Manager
No. 57, Park Avenue 2, Science Park
Hsinchu, 300
Taiwan

Letter dated: February 5, 2013

Re: K122183
Trade/Device Name: Augment and Screw, PSA Type
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 20, 2012
Received: December 26, 2012

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K122183

Device Name: Augment and Screw, PSA Type

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Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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